CATHETER WITH ABLATION NEEDLE AND MAPPING ASSEMBLY

BACKGROUND OF THE INVENTION

Radiofrequency (RF) ablation of cardiac and other tissue is a well known method for creating thermal injury lesions at the tip of an electrode. Radiofrequency current is delivered between a skin (ground) patch and the electrode. Electrical resistance at the electrode-tissue interface results in direct resistive heating of a small area, the size of which depends upon the size of the electrode, electrode tissue contact, and current (density). See Avitall B, Helms R. Determinants or Radiofrequency-Induced Lesion Size in Huang SKS, Wilber DJ (eds.): Radiofrequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications, 2nd ed. Armonk, NY, Futura Publishing Company, Inc., 2000: 47-80. Further tissue heating results from conduction of heat within the tissue to a larger zone. Tissue heated beyond a threshold of approximately 50-55°C is irreversibly injured (ablated). See Nath S, and Haines DE. Pathophysiology of Lesion Formation by Radiofrequency Catheter Ablation, in Huang SKS, Wilber DJ (eds.): Radiofrequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications, 2nd ed. Armonk, NY, Futura Publishing Company, Inc., 2000: 26-28.

Resistive heating is caused by energy absorption due to electrical resistance. Energy absorption is related to the square of current density and inversely with tissue conductivity. Current density varies with conductivity and voltage and inversely with the square of radius from the ablating electrode. Therefore, energy absorption varies with conductivity, the square of applied voltage, and inversely with the fourth power of radius from the electrode. Resistive heating, therefore, is most heavily influenced by radius, and penetrates a very small distance from the ablating electrode. The rest of the lesion is created by thermal conduction from the area of resistive heating. See Lin J, Physical Aspects of Radiofrequency Ablation, in Huang SKS, Wilber DJ (eds.): Radiofrequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications, 2nd ed. Armonk, NY, Futura Publishing Company, Inc., 2000: 14-17. This imposes a limit on the size of ablation lesions that can be delivered from a surface electrode.

Theoretical methods to increase lesion size would include increasing electrode diameter, increasing the area of electrode contact with tissue, increasing tissue conductivity and

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penetrating the tissue to achieve greater depth and increase the area of contact, and delivering RF until maximal lesion size has been achieved (60-90 seconds for full maturation).

The electrode can be introduced to the tissue of interest directly (for superficial/skin structures), surgically, endoscopically, laparoscopically or using percutaneous transvascular (catheter-based) access. Catheter ablation is a well-described and commonly performed method by which many cardiac arrhythmias are treated. See Miller J M, Zipes D P. Management of the Patient with Cardiac Arrhythmias. In Braunwald E, Zipes D, Libby P (eds): Heart Disease: A Textbook of Cardiovascular Medicine, 6th Ed. Philadelphia, PA, W.B. Saunders Company, 2001: p742-752. Needle electrodes have been described for percutaneous or endoscopic ablation of solid-organ tumours, lung tumours, and abnormal neurologic structures. See, for example, McGahan J P, Schneider P, Brock J M, Tesluk H. Treatment of Liver Tumors by Percutaneous Radiofrequency Electrocautery. Seminars in Interventional Radiology 1993; 10: 143-149; Rossi S, Fornari F, Buscarini L. Percutaneous Ultrasound-Guided Radiofrequency Electrocautery for the Treatment of Small Hepatocellular Carcinoma. J Intervent Radiol 1993; 8: 97-103; and Livraghi T, Goldberg S N, Lazzaroni S, Meloni F, Monti F, Solbiati L. Saline-enhanced RF tissue ablation in the treatment of liver Metastases. Radiology 1995; 197(P): 140 (abstr)].

Catheter ablation is sometimes limited by insufficient lesion size. See de Bakker J M T, van Capelle F J L, Janse M J et al. Macroreentry in the infarcted human heart: mechanism of ventricular tacycardias with a “focal” activation pattern. J Am Coll Cardiol 1991; 18:1005-1014; Kaltenbrunner W, Cardinal R, Dubuc M et al. Epicardial and endocardial mapping of ventricular tachycardia in patients with myocardial infarction. Is the origin of the tachycardia always subendocardially localized? Circulation 1991; 84: 1058-1071. Stevenson W G, Friedman P L, Sager P T et al. Exploring postinfarction reentrant ventricular tachycardia with entrainment mapping. J Am coll Cardiol 1997; 29: 1180-1189. Ablation of tissue from an endovascular approach results not only in heating of tissue, but of heating of the electrode. When the electrode reaches critical temperatures, denaturation of blood proteins causes coagulum formation. Impedance can then rise and limit current delivery. Within tissue, overheating can cause evaporation of tissue or blood water and steam bubble formation (steam “pops”) with risk of uncontrolled tissue destruction or undesirable perforation of bodily structures. In cardiac ablation, clinical success is sometimes hampered by inadequate lesion depth and transverse diameter even when using catheters with active cooling of the tip. See Soejima K, Delacretaz E,

Suzuki M et al. Saline-cooled versus standard radiofrequency catheter ablation for infarct-related ventricular tachycardias. Circulation 2001; 103:1858-1862. Theoretical solutions have included increasing the electrode size (increasing contact surface and increasing convective cooling by blood flow), improving electrode-tissue contact, actively cooling the electrode with fluid infusion, changing the material composition of the electrode to improve current delivery to tissue, and pulsing current delivery to allow intermittent cooling.

Needle electrodes improve contact with tissue and allow deep penetration of current delivery to areas of interest. Ablation may still be hampered by the small surface area of the needle electrode such that heating occurs at low power, and small lesions are created.

Additionally, it is desirable to map the electrical activity in the heart before, during or after ablation. If the mapping can be performed with the same catheter used for ablation, the user avoids the need for catheter exchange. Moreover, it is desirable to include a mapping assembly on the catheter comprising a plurality of electrodes that can be used to simultaneously map electrical activity at different positions within the heart to provide more efficient mapping.

SUMMARY OF THE INVENTION

The present invention addresses the above concerns by providing a catheter that creates enhanced lesions using a needle electrode and can simultaneously map electrical activity at a plurality of points using an enhanced mapping assembly. The catheter comprises an elongated catheter body having at least one lumen extending longitudinally therethrough. A needle control handle is provided at the proximal end of the catheter body. A needle electrode assembly extends through the catheter body and needle control handle and has a proximal end attached to the needle control handle and a distal end within the distal end of the catheter body. A mapping assembly is mounted at the distal end of the catheter body and comprises at least two flexible spines. Each spine has a proximal end attached at the distal end of the catheter body and a free distal end. Each spine carries at least one electrode. The distal end of the needle electrode assembly is extendable past the proximal end of the mapping assembly upon manipulation of the needle control handle.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side plan view of an embodiment of a catheter of the present invention.

FIG. 2 is a side cross-sectional view of the needle control handle where the needle electrode assembly is in a retracted position.

FIG. 3 is a schematic side cross-sectional view of the distal end of the distal shaft, including the proximal end of the mapping assembly.

FIG. 4 is a side cross-sectional view of the thermocouple mounted in the needle electrode assembly.

FIG. 5 is a side cross-sectional view of the catheter body, including the junction between the proximal shaft and the distal shaft.

FIG. 6 is an end cross-sectional view of the distal shaft of the catheter body shown in FIG. 5 along line 6-6.

FIG. 7 is an end cross-sectional view of the proximal shaft of the catheter body shown in FIG. 5 along line 7-7.

FIG. 8 is a side view of a mapping assembly according to the invention.

FIG. 9 is a perspective view of a support structure according to the present invention.

FIG. 10 is a side cross sectional view of a portion of the catheter tip section showing one means for attaching the puller wire.

FIG. 11 is a top cross sectional views of a preferred puller wire anchor.

FIG. 12 is a side cross sectional views of the puller wire anchor of FIG. 11.

DETAILED DESCRIPTION

As shown in FIG. 1, the catheter **10** comprises an elongated catheter body **12** having a proximal shaft **13** and a distal shaft **14**, a mapping assembly **15** mounted at the distal end of the distal shaft, a deflection control handle **16** attached to the proximal end of the proximal shaft, and a needle control handle **17** attached indirectly to the catheter body proximal to the deflection control handle.

With reference to FIGs. 5 and 7, the proximal shaft **13** comprises a single, central or axial lumen **18**. The proximal shaft **13** is flexible, i.e., bendable, but substantially non-compressible along its length. The proximal shaft **13** may be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **22** made of polyurethane or nylon. The outer wall **22** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the proximal shaft **13** so that, when the deflection control handle **16** is rotated, the distal shaft **14** of the catheter **10** will rotate in a corresponding manner.

The outer diameter of the proximal shaft **13** is not critical, but is preferably no more than about 8 French. Likewise the thickness of the outer wall **22** is not critical. In the depicted embodiment, the inner surface of the outer wall **22** is lined with a stiffening tube **20**, which can be made of any suitable material, preferably polyimide. The stiffening tube **20**, along with the braided outer wall **22**, provides improved torsional stability while at the same time minimizing the wall thickness of the catheter, thus maximizing the diameter of the single lumen. The outer diameter of the stiffening tube **20** is about the same as or slightly smaller than the inner diameter of the outer wall **22**.

As shown in FIGs. 5 and 6, the distal shaft **14** comprises a short section of tubing **19** having three lumens, namely an infusion lumen **30**, a puller wire lumen **32** and a lead wire lumen **34**. The tubing **19** is made of a suitable non-toxic material that is preferably more flexible than the proximal shaft **13**. A presently preferred material for the tubing **19** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The outer diameter of the distal shaft **14**, like that of the proximal shaft **13**, is preferably no greater than about 8 French.

A preferred means for attaching the proximal shaft **13** to the distal shaft **14** is illustrated in FIG. 5. The proximal end of the distal shaft **14** comprises an inner counter bore **24** that receives the outer surface of the stiffener **20**. The distal shaft **14** and proximal shaft **13** are attached by glue or the like. Other methods for attaching the proximal shaft **13** to the distal shaft **14** can be used in accordance with the invention.

The stiffening tube **20** is held in place relative to the outer wall **22** at the proximal shaft **13**. In a preferred construction of the proximal shaft **13**, a force is applied to the proximal end of the stiffening tube **20**, which causes the distal end of the stiffening tube **20** to firmly push

against the counter bore **24**. While under compression, a first glue joint is made between the stiffening tube **20** and the outer wall **22** by a fast drying glue, e.g. Super Glue®. Thereafter a second glue joint is formed between the proximal ends of the stiffening tube **20** and outer wall **22** using a slower drying but stronger glue, e.g., polyurethane.

The depicted catheter includes a mechanism for deflecting the distal shaft **14** of the catheter body **12**. In the depicted embodiment, a puller wire **42** extends into the puller wire lumen **32** of the distal shaft **14**. The puller wire **42** is anchored at its proximal end to the deflection control handle **16** and anchored at its distal end to the distal shaft **14**. The puller wire **42** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **42**. The puller wire **42** preferably has a diameter ranging from about 0.006 to about 0.010 inches.

Referring to FIG. 5, the compression coil **44** extends from the proximal end of the proximal shaft **13** to the proximal end of the distal shaft **14**. The compression coil **44** is made of any suitable metal, preferably stainless steel. The compression coil **44** is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil **44** is preferably slightly larger than the diameter of the puller wire **42**. For example, when the puller wire **42** has a diameter of about 0.007 inches, the compression coil **44** preferably has an inner diameter of about 0.008 inches. The Teflon® coating on the puller wire **42** allows it to slide freely within the compression coil **44**. Along its length, the outer surface of the compression coil **44** is covered by a flexible, non-conductive sheath **26** to prevent contact between the compression coil **44** and any of the lead wires **129** or needle electrode assembly **46**. A non-conductive sheath **26** made of polyimide tubing is presently preferred. As shown in FIG. 5, the compression coil **44** is anchored at its proximal end to the proximal end of the stiffening tube **20** in the proximal shaft **13** by glue to form a glue joint **50** and at its distal end to the distal shaft **14** in the puller wire lumen **32**.

The puller wire **42** extends into the puller wire lumen **32** of the distal shaft **14**. Preferably the puller wire **42** is anchored at its distal end to the side of the distal shaft **14**, as shown in FIGs. 10 to 12. In this embodiment, a T-shaped anchor **93** is formed which comprises a short piece of tubular stainless steel **94**, e.g., hypodermic stock, which is fitted over the distal end of the puller wire **42** and crimped to fixedly secure it to the puller wire. The distal end of the tubular stainless steel **94** is fixedly attached, e.g., by welding, to a stainless steel cross-piece **96**,

such as stainless steel ribbon or the like. The cross-piece **96** sits in a notch **98** in a wall of the distal shaft **14** that extends into the second lumen **32**. The stainless steel cross-piece **96** is larger than the notch **98** and, therefore, cannot be pulled through the notch. The portion of the notch **98** not filled by the cross-piece **96** is filled with glue or the like, preferably a polyurethane glue, which is harder than the material of the distal shaft **14**. Rough edges, if any, of the cross-piece **96** are polished to provide a smooth, continuous surface with the outer surface of the distal shaft **14**.

With further reference to FIG. 5, within the distal shaft **14**, and distal to the glue joint **50**, the turns of the compression coil are expanded longitudinally. Such expanded turns **49** are both bendable and compressible and preferably extend for a length of about 0.5 inch. The puller wire **42** extends through the expanded turns **49** then into a plastic, preferably Teflon®, sheath **81**, which prevents the puller wire from cutting into the wall of the distal shaft **14** when the distal shaft is deflected.

Any other suitable technique for anchoring the puller wire **42** in the distal shaft **14** can also be used. Alternatively, other means for deflecting the distal region can be provided, such as the deflection mechanism described in U.S. Patent No. 5,537,686, the disclosure of which is incorporated herein by reference.

Longitudinal movement of the puller wire **42** relative to the catheter body **12**, which results in deflection of the distal shaft **14**, is accomplished by suitable manipulation of the control handle **16**. Examples of suitable control handles for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502, 5,897,529 and 6,575,931, the entire disclosures of which are incorporated herein by reference.

If desired, the catheter can include two or more puller wires (not shown) to enhance the ability to manipulate the distal shaft **14**. In such an embodiment, a second puller wire and a surrounding second compression coil extend through the proximal shaft **13** and into separate off-axis lumens (not shown) in the distal shaft. Suitable deflection control handles for use with a catheter having more than one puller wire are described in U.S. Patent Nos. 6,123,699, 6,171,277, and 6,183,463, the disclosures of which are incorporated herein by reference.

As shown in FIG. 3, a needle electrode assembly **46** is provided. The needle electrode assembly **46** is used to ablate tissue while simultaneously injecting saline or other fluid to conduct the ablation energy, thereby creating a theoretic increase in the effective size of the

electrode. The needle electrode assembly **46** is extendable and retractable, and may be moved by manipulation of the needle control handle **17**, as described further below. FIG. 3 depicts the needle electrode assembly **46** in an extended position as it would be to ablate tissue. The distal end of the needle electrode assembly **46** may be withdrawn into the infusion lumen **30** to avoid injury, particularly during the time that the catheter is inserted through the vasculature of the body and during the time in which the catheter is removed from the body.

The needle electrode assembly **46** comprises a proximal tubing **33** joined, directly or indirectly, to a generally rigid, electrically-conductive distal tubing **35**, as shown in FIG. 3. The generally rigid nature of the distal tubing **35** allows it to pierce tissue in order to increase its effectiveness during ablation. In an exemplary embodiment, the distal tubing **35** is formed of Nitinol or stainless steel, and, as illustrated in FIG. 3, is preferably formed with a beveled edge **36** at the distal tip of the needle electrode assembly **46** to enhance its ability to pierce tissue. The proximal tubing **33** is preferably more flexible than the distal tubing **35** to allow the proximal tubing to bend as necessary with the flexible proximal shaft **13** of the catheter body **12**, for instance when the catheter is inserted into the vasculature of the body. The proximal tubing **33** of the needle electrode assembly **46** is preferably made of polyimide or polyether etherketone (PEEK), but can be made of any other suitable biocompatible material, such as plastic or metal.

A needle electrode lead wire **210** is electrically connected at its distal end to the electrically-conductive distal tubing **35** for supplying radio frequency energy or other suitable ablation energy to the distal tubing. The needle electrode lead wire **210** is soldered, welded or otherwise attached to the outside of the distal tubing **35**, but could be attached elsewhere to the distal tubing. The proximal end of the needle electrode lead wire **210** is attached to a suitable connector **67**, which in turn is connected to a suitable source of ablation energy (not shown).

Additionally, a temperature sensor is provided for measuring the temperature of the tissue being ablated by the needle electrode assembly **46** before, during or after ablation. Any conventional temperature sensor, e.g., a thermocouple or thermistor, may be used. In the depicted embodiment, the temperature sensor comprises a thermocouple **200** formed by an enameled wire pair, as best shown in FIG. 4. One wire of the wire pair is a copper wire **202**, e.g., a number 40 copper wire. The other wire of the wire pair is a constantan wire **204**. The wires **202** and **204** of the wire pair are electrically isolated from each other except at their distal

ends, where they are twisted together, covered with a short piece of plastic tubing **206**, e.g., polyimide, and covered with epoxy. The plastic tubing **206** is then glued or otherwise attached to the inside wall of the distal tubing **35** of the needle electrode assembly **46**, as best shown in FIG. 3. The proximal ends of the wires **202** and **204** extend out the proximal end of the distal tubing **35** and are attached to an appropriate connector (not shown) connectable to a suitable temperature monitor (not shown). In an alternative embodiment, the copper wire **202** of the thermocouple can also be used as the lead wire for the needle electrode assembly **46**

The proximal tubing **33** of the needle electrode assembly **46** extends from the needle control handle **17**, through the deflection control handle **16**, through the proximal shaft **13**, and into the infusion lumen **30** of the distal shaft **14**. The proximal end of the distal tubing **35** is spaced slightly from the distal end of the proximal tubing **33** and extends through the infusion lumen **30** of the distal shaft **14**. The proximal and distal tubings **33** and **35** are mounted, preferably coaxially, within an outer plastic tube **48**. The outer plastic tube **48** can be glued or otherwise attached to the proximal and distal tubings to form a single structure that, as described below, is longitudinally moveable relative to the catheter body **12**. The outer plastic tube **48** extends through the catheter body **12** with the proximal tubing and protects the needle electrode lead wire **210** and thermocouple wires **202** and **204**, which extend between the proximal tubing **33** and outer plastic tube **48**, when the needle electrode assembly **46** is moved relative to the catheter body. The needle electrode lead wire **210** and thermocouple wires **202** and **204** extend out through a hole (not shown) in the outer plastic tube **48** within the deflection control handle **16** and are attached to appropriate connectors, as noted above.

FIG. 3 shows one arrangement for joining the outer plastic tube **48** to the proximal and distal tubings **33** and **35**. Specifically, a small piece of plastic tubing **45**, for example, polyimide tubing, is placed over the discontinuity between the proximal and distal tubings **33** and **35** and attached to the proximal and distal tubings by polyurethane glue or the like to form a single infusion passage through which saline or other fluid can pass from the proximal tubing to the distal tubing. The small piece of plastic tubing **45** helps to protect the thermocouple wires **202** and **204** and the needle electrode lead wire **210**. A small, preferably non-conductive, spacer **43** is mounted between the distal tubing **35** and the distal end of the outer plastic tube **48**, and optionally glued in place. The spacer **43** prevents bodily fluid from entering into the distal end of the needle electrode assembly **46**,

In an exemplary embodiment, the proximal tubing **33** of the needle electrode assembly **46** has an inner diameter of 0.014 inch and an outer diameter of 0.016 inch. The distal tubing **35** has an inner diameter of 0.014 inch and an outer diameter of 0.018 inch and a length of about 1.0 inch. Further, the distal tubing **35** extends past the distal end of the distal shaft **14** about 14 mm. The small plastic tubing **45** has an inner diameter of 0.022 inch and an outer diameter of 0.024, the outer plastic tube **48** has an inner diameter of 0.025 inch and an outer diameter of 0.035 inch, and the plastic spacer **43** has an inner diameter of 0.017 inch and an outer diameter of 0.024 inch.

Within the catheter body **12**, the needle electrode assembly **46**, comprising the proximal tubing **33**, distal tubing **35**, spacer **43**, plastic tubing **45** and outer plastic tube **48**, is slidably mounted, preferably coaxially, within a protective tube **47** that is stationary relative to the catheter body. The protective tube **47**, which is preferably made of polyimide, serves to prevent the needle electrode assembly **46** from buckling during extension and retraction of the needle electrode assembly relative to the catheter body **12**. The protective tube **47** additionally serves to provide a fluid-tight seal surrounding the needle electrode assembly **46**. Within the deflection control handle **16**, the protective tube **47** and needle electrode assembly **46** extend into a protective shaft **66**, which is preferably made of polyurethane.

Other needle electrode assembly designs are contemplated within the scope of the invention. For example, the needle electrode assembly can comprise a single electrically-conductive tube, such as a Nitinol tube, that extends from the needle control handle **17** to the distal end of the catheter. Such a design is described in U.S. Patent Application No. 09/711,648, entitled "Injection Catheter with Needle Electrode," the disclosure of which is incorporated herein by reference.

Longitudinal movement of the needle electrode assembly **46** is achieved using the needle control handle **17**. The needle electrode assembly **46** and protective tube **47** extend from the deflection control handle **16** to the needle control handle **17** within the protective shaft **66.**

As illustrated in FIG. 2, in one embodiment the needle control handle **17** comprises a generally cylindrical outer body **80** having proximal and distal ends, a piston chamber **82** extending a part of the way therethrough, and a needle passage **83** extending a part of the way therethrough. The piston chamber **82** extends from the proximal end of the handle part way into the body **80**, but does not extend out the distal end of the body. The needle passage **83**, which

has a diameter less than that of the piston chamber **82**, extends from the distal end of the piston chamber to the distal end of the outer body **80**.

A piston **84**, having proximal and distal ends, is slidably mounted within the piston chamber **82**. A proximal fitting **86** is mounted in and fixedly attached to the proximal end of the piston **84**. The proximal fitting **86** includes a tubular distal region **87** that extends distally from the main body of the proximal fitting. The piston **84** has an axial passage **85** through which the proximal tubing **33** of the needle electrode assembly **46** extends, as described in more detail below. A compression spring **88** is mounted within the piston chamber **82** between the distal end of the piston **84** and the outer body **80**. The compression spring **88** can either be arranged between the piston **84** and outer body **80**, or can have one end in contact with or fixed to the piston, while the other end is in contact with or fixed to the outer body.

The proximal tubing **33**, outer plastic tube **48**, protective tube **47** and protective shaft **66** extend from the deflection control handle **16** into the distal end of the needle passage **83**, as best shown in AREA A of FIG. 2. Within the needle passage **83**, the proximal tubing **33**, outer plastic tube **48**, protective tube **47** and protective shaft **66** extend into a first metal tube **90**, which is preferably made of stainless steel. If desired, the first metal tube **90** could instead be made of a rigid plastic material. The first metal tube **90** is secured to the outer body **80** of the needle control handle **17** by a set screw **101** or any other suitable means. The protective shaft **66** terminates at its proximal end within the first metal tube **90**.

A second metal tube **91** is provided with its distal end mounted, preferably coaxially, inside the proximal end of the first metal tube **90** and with its distal end abutting the proximal end of the protective shaft **66**. The second metal tube **91** is fixed in place relative to the first metal tube **90** by the set screw **101**. The second metal tube **91**, like the first metal tube **90**, could alternatively be made of a rigid plastic material.

The proximal end of the second metal tube **91** is mounted, preferably coaxially, around the distal end of the tubular distal region **87** of the proximal fitting **86**, with the second metal tube being longitudinally movable relative to the tubular distal region **87**. Accordingly, when the piston **84** is moved distally relative to the outer body **80**, the tubular distal region **87** moves distally into the second metal tube **91**. As shown in AREA B of FIG. 2, the proximal tubing **33** and outer plastic tube **48** extend through the second metal tube **91** and into the tubular distal region **87** of the proximal fitting **86**. The outer plastic tube **48** terminates in and is fixedly

attached to the proximal fitting **86** to thereby attach the outer plastic tube, and thus the needle electrode assembly **46**, to the piston **84**. Within the proximal fitting **86**, the proximal tubing **33** extends out of the outer plastic tube **48** and into a first protective sheath **31**, as shown in AREA C of FIG. 2, and is connected to a luer connector **65**, which is connected to an irrigation pump or other suitable fluid infusion source (not shown), as is known in the art. Similarly, the needle electrode lead wire **210** and the thermocouple wires **202** and **204** extend out of the outer plastic tube **48** and into a second protective sheath **29**, as also shown in AREA C of FIG. 2, which is connected to a suitable connector **67**, such as a 10-pin electrical connector, for connecting the needle electrode lead wire to a source of ablation energy and the thermocouple wires to a suitable monitoring system.

In use, force is applied to the piston **84** to cause distal movement of the piston relative to the outer body **80**, which compresses the compression spring **88**. This movement causes the needle electrode assembly **46** to correspondingly move distally relative to the outer body **80**, protective shaft **66**, protective tube **47**, proximal shaft **13**, and distal shaft **14** so that the distal tubing **35** of the needle electrode assembly extends outside the distal end of the distal shaft. When the force is removed from the piston **84**, the compression spring **88** pushes the piston proximally to its original position, thus causing the distal tubing **35** of the needle electrode assembly **46** to retract back into the distal end of the distal shaft **14**. Upon distal movement of the piston **84**, the tubular distal region **87** of the proximal fitting **86** moves distally into the second metal tube **91** to prevent the proximal tubing **33** and the outer plastic tube **48** of the needle electrode assembly **46** from buckling within the axial passage **85**.

The piston **84** further comprises a longitudinal slot **100** extending along a portion of its outer edge. A securing means **102**, such as a set screw, pin, or other locking mechanism, extends through the outer body **80** and into the longitudinal slot **100**. This design limits the distance that the piston **84** can be slid proximally out of the piston chamber **82**. When the needle electrode assembly **46** is in the retracted position, preferably the securing means **102** is at or near the distal end of the longitudinal slot **100**.

The proximal end of the piston **84** has a threaded outer surface **104**. A circular thumb control **106** is rotatably mounted on the proximal end of the piston **84**. The thumb control **106** has a threaded inner surface **108** that interacts with the threaded outer surface **104** of the piston. The thumb control **106** acts as a stop, limiting the distance that the piston **84** can be pushed into

the piston chamber **82**, and thus the distance that the needle electrode assembly **46** can be extended out of the distal end of the catheter. The threaded surfaces of the thumb control **106** and piston **84** allow the thumb control to be moved closer or farther from the proximal end of the outer body **80** so that the extension distance of the needle electrode assembly **46** can be controlled by the physician. A securing means, such as a tension screw **110** is provided in the thumb control **106** to control the tension between the thumb control and piston **84**. As would be recognized by one skilled in the art, the thumb control **106** can be replaced by any other mechanism that can act as a stop for limiting the distance that the piston **84** extends into the piston chamber **82**, and it is not necessary, although it is preferred, that the stop be adjustable relative to the piston.

As noted above, the mapping assembly **15** is mounted on the distal end of the distal shaft **14.** With reference to FIGs. 3 and 8, the mapping assembly **15** comprises two or more flexible spines **118.** Each spine **118** has a proximal end attached to the distal end of the catheter body **12** and a free distal end, i.e., the distal end is not attached to any of the other spines, to the catheter body, or to any other structure that confines movement of the distal end of that spine. As will be recognized by one skilled in the art, the number of spines **118** can vary as desired depending on the particular application, so that the mapping assembly **15** has at least two spines, preferably at least three spines, more preferably at least five spines and as many as eight or more spines. The spines **118** are moveable between an expanded arrangement, wherein, for example, each spine arcs outward from the distal end of the catheter body **12**, as shown in FIG. 8, and a collapsed arrangement (not shown), wherein, for example, each spine is disposed generally along a longitudinal axis of the catheter body so that the spines are capable of fitting within a lumen of a guiding sheath. As described in more detail below, each spine **118** carries at least one electrode, preferably a ring electrode, such that when the spines are positioned in contact with heart tissue, each spine is capable of obtaining electrical and mechanical data.

In the embodiment shown in FIG. 8, the mapping assembly **15** includes five spines **118,** and each spine has a pre-formed configuration in which the spine arcs outwardly from the catheter body **12.** However, other spine shapes and configurations are contemplated within the invention. With reference to FIG. 3, each spine **118** comprises a support arm **124** and a non-conductive covering **134** in surrounding relation to the support arm **124**. The support arm **124** comprises a metal or plastic material that has shape memory, such that the support arm forms an

initial shape (i.e., part of the expanded configuration) when no external forces are applied, forms a deflected shape (e.g., part of the collapsed configuration) when external force is applied, and returns to its initial shape when the external force is released. In one embodiment, each support arm **124** comprises a superelastic material, for example, a nickel-titanium alloy such as nitinol. In a preferred embodiment, the non-conductive covering **134** comprises a biocompatible plastic tubing, such as polyurethane or polyimide tubing. The non-conductive covering **134** may be glued to the support arm **132** or attached indirectly by being glued to the distal end of the distal tubing **35**. The non-conductive covering **134** may be attached to the support arm **124** by any other suitable method.

As noted above, each spine **118** carries at least one electrode mounted along its length. In the depicted embodiment, four ring electrodes **125** are mounted on the non-conductive covering **134** of each spine **118**, but fewer or additional ring electrodes may be used as desired. Each ring electrode **125** has a length preferably up to about 2 mm, more preferably from about 0.5 mm to about 1 mm. Preferably the ring electrodes **125** are generally evenly-spaced along the length of each spine **118**.

Each ring electrode **125** is electrically connected to an electrode lead wire **129**, which in turn is electrically connected to a connector (not shown), which can be incorporated into the deflection control handle **16** or provided outside of the catheter. The connector is connected to an appropriate mapping or monitoring system (not shown). Each electrode lead wire **129** extends from the connector, through the deflection control handle **16**, through the central lumen **18** in the proximal shaft **13** of the catheter body **12**, through the lead wire lumen **34** of the distal shaft **14**, and into the non-conductive covering **134** of one of the spines **118**, where it is attached to its corresponding ring electrode **125**. Within the proximal shaft **13** and deflection control handle **16**, the lead wires **129** extend through a protective tube **70**, which can be eliminated if desired.

Each lead wire **129**, which includes a non-conductive coating over almost all of its length, is attached to its corresponding ring electrode **125** by any suitable method. An exemplary method for attaching a lead wire **129** to a ring electrode **125** involves first making a small hole through an outer wall of the non-conductive covering **134**. Such a hole can be created, for example, by inserting a needle through the non-conductive covering **134** and heating the needle sufficiently to form a permanent hole. The lead wire **129** is then drawn through the hole by

using a microhook or the like. The end of the lead wire **129** is then stripped of any coating and welded to the underside of the ring electrode **125**, which is then slid into position over the hole and fixed in place with polyurethane glue or the like. Alternatively, each ring electrode **125** may be formed by wrapping the lead wire **129** around the non-conductive covering **134** a number of times and stripping the lead wire of its own non-conductive coating on its outwardly facing surfaces. In such an instance, the lead wire **129** functions as a ring electrode.

In the depicted embodiment, two of the spines **118** each carry a marker band **130** to help the user identify the orientation of the mapping assembly **15** under fluoroscopy. Each marker band **130** comprises a metal ring (e.g., a ring electrode not attached to a lead wire) of sufficient radiopacity. The marker bands **130** may be placed along any part of the spine **118**, as long as they are not in contact with any of the ring electrodes **125**. Preferably, a first marker band **130a** is placed on a first spine **118a** between the most proximal ring electrode **125a** and the distal shaft **14**, and a second marker band **130b** is placed on a second spine **118b** between the most proximal ring electrode **125a** and the second most proximal ring electrode **125b**.

In the depicted embodiment, the spines **118** of the mapping assembly **15** are supported and given their desired shape by a support structure **120** comprising a base **122** and plurality of support arms **124** extending from the base, as best shown in FIG. 9. The base **122** of the support structure **120** is generally cylindrically shaped for mounting over the distal end of the tubing **19** of the distal shaft **14**. The support arms **124** each have a proximal end attached to the base **122** and a free distal end, as described above. The number of support arms **124** on the support structure corresponds to the desired number of spines **118** on the mapping assembly, and in the depicted embodiment is five.

In a preferred embodiment, the support structure **120** is manufactured from a single metal tube, and thus has a unitary structure. In a particularly preferred embodiment, the support structure **120** is manufactured from a nickel-titanium alloy, for instance, Nitinol. Preferably, the base is a right circular cylinder and has a diameter slightly larger than the distal end of the distal shaft **14**.

In the depicted embodiment, each support arm **124** is tapered slightly from its proximal end to its distal end, which allows for greater distal flexibility while maintaining the desired curvature at the proximal end. Each support arm **124** also includes a disc-shaped tip **127**, which

provides more surface area for the distal end of the support arm **124** to be glued to its corresponding non-conductive covering **134**.

During assembly, the base **122** of the support structure **120** is mounted over the distal end of the tubing **19** of the distal shaft **14**. Non-conductive coverings **134** are introduced over the support arms **124** to form the spines **118** of the mapping assembly **15**. After the ring electrodes **125** are mounted on the spines **118** as described above and the other desired components are assembled within the catheter, a piece of tubular plastic **208** is mounted over the base **122** of the support structure **120** and optionally glued in place. The piece of tubular plastic **208** also covers the proximal ends of the non-conductive coverings **134**.

Other methods and structures for forming and supporting the mapping assembly are within the scope of the invention. An example of an alternative design for the mapping assembly according to the invention is described in U.S. Patent Application No. 10/040,932, entitled "Catheter Having Multiple Spines Each Having Electrical, Mapping and Location Sensing Capabilities," the disclosure of which is incorporated herein by reference.

In the depicted embodiment, as shown in FIG. 3, the catheter further includes at least one location sensor **140**. The location sensor **140** is used to determine the coordinates of the mapping assembly **15** at each instant when the mapping assembly **15** is being used to collect one or more electrical mapping data points. As a result, both electrical and locational data can be obtained for each data point that is mapped. In the depicted embodiment, a single location sensor **140** is mounted in the distal end of the distal shaft **14** within the cylindrical base **122** of the support structure **120**. Alternatively, the catheter can include multiple location sensors **140**, one mounted within each spine **118** of the mapping assembly **15**, as described in U.S. Patent Application No. 10/040,932, entitled "Catheter Having Multiple Spines Each Having Electrical, Mapping and Location Sensing Capabilities," the entire disclosure of which is incorporated herein by reference.

The location sensor **140** is connected to a corresponding sensor cable **74**. The sensor cable **74** extends, along with the lead wires **129**, through the lead wire lumen **34** of the distal shaft **14**, and through the proximal shaft **13** within the protective tube **70** and then into the deflection control handle **16** and out of the proximal end of the deflection control handle within an umbilical cord (not shown) to a sensor control module (not shown) that houses a circuit board (not shown). Alternatively, the circuit board can be housed within the control handle **16**, for

example, as described in U.S. Patent No. 6,024,739, the disclosure of which is incorporated herein by reference. The sensor cable **74** comprises multiple wires encased within a plastic covered sheath. In the sensor control module, the wires of the sensor cable **74** are connected to the circuit board. The circuit board amplifies the signal received from the location sensor **140** and transmits it to a computer in a form understandable by the computer by means of a sensor connector at the proximal end of the sensor control module. Also, because the catheter is designed for single use only, the circuit board preferably contains an EPROM chip that shuts down the circuit board approximately twenty-four hours after the catheter has been used. This prevents the catheter, or at least the location sensor **140**, from being used twice.

Preferably the location sensor **140** is an electromagnetic location sensor. For example, the location sensor **140** may comprise a magnetic-field-responsive coil, as described in U.S. Patent No. 5,391,199, or a plurality of such coils, as described in International Publication WO 96/05758. The plurality of coils enables the six-dimensional coordinates (i.e. the three positional and the three orientational coordinates) of the location sensor **140** to be determined. Alternatively, any suitable location sensor known in the art may be used, such as electrical, magnetic or acoustic sensors. Suitable location sensors for use with the present invention are also described, for example, in U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, and 5,568,809, International Publication Nos. WO 95/02995, WO 97/24983, and WO 98/29033, and U.S. Patent Application Serial No. 09/882,125 filed June 15, 2001, entitled "Position Sensor Having Core with High Permeability Material," the disclosures of which are incorporated herein by reference.

Using this technology, the physician can visually map a heart chamber. This mapping is done by advancing the distal shaft **14** into a heart chamber until contact is made with the heart wall. This position is recorded and saved. The distal shaft **14** is then moved to another position in contact with the heart wall and again the position is recorded and saved.

The location sensor **140** can be used alone or more preferably in combination with the ring electrodes **125**. By combining the location sensor **140** and electrodes **125**, a physician can simultaneously map the contours or shape of the heart chamber, the electrical activity of the heart, and the extent of displacement of the catheter and hence identify the presence and location of the ischemic tissue. Specifically, the location sensor **125** is used to monitor the precise

location of the distal end of the catheter in the heart and the extent of catheter displacement. The ring electrodes **125** are used to monitor the strength of the electrical signals at that location.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningful departing from the principal, spirit and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.